IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION **THIS DOCUMENT RELATES TO: ETHICON WAVE 3 CASES:** ***Identified on Exhibit A to Memorandum***	**MDL No. 2327** **JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

REPLY MEMORANDUM IN SUPPORT OF PLAINTIFFS' MOTION TO EXCLUDE THE GENERAL CAUSATION OPINIONS OF BRIAN J. FLYNN, MD

Plaintiffs submit this Reply in further support of their Motion to Exclude the General Causation Opinions of Brian Flynn, M.D (Doc. No. 2854).

INTRODUCTION

Defendants propose to offer into evidence Dr. Flynn's same opinions from Wave 1 regarding the safety and efficacy of five different products: TVT-R, TVT-O, TVT-Secur, Prolift and Prolift+M.

Dr. Flynn offers opinions regarding his review of the medical literature. Plaintiffs demonstrated in their Motion that these opinions are the product of an unreliable methodology. For these reasons, the Court in Wave 1 excluded many of the *exact same* opinions here. Again, Defendants cannot provide even one sentence, from any of Dr. Flynn's five reports, where he discusses or explains why he discounted any of the contrary evidence – because he ignored it. Instead, Defendants misapply the Court's earlier rulings and erroneously argue that Dr. Flynn's unreliable methodology is not relevant to the admissibility of his opinions regarding the medical literature. *See* Def's. Resp. in Opp. (Doc. No. 2913).

In their Response, Defendants admit many of these errors exist. For example, Defendants concede in their briefing that:

(1) Dr. Flynn employed the same [unreliable] methodology in all five of his reports.

(2) Dr. Flynn purposely chose to only discuss one-sided literature in all five of his reports.

(3) Dr. Flynn did not discuss a single piece of evidence contrary to his opinions in any of his five reports.

(4) Dr. Flynn "didn't have time" to adequately review a number of important studies of which he was aware and which were contrary to his opinions.

(5) Dr. Flynn concluded that he had "read enough" medical literature and would not change his opinions based on any evidence contrary to his opinions.

Importantly, Dr. Flynn's reports have not changed since Wave 1, and the Court has already ruled on many of the arguments here. Regarding Dr. Flynn's one-sided review of the medical literature, the Court noted "Dr. Flynn focused only on medical literature that supported his opinions, ignoring relevant, contrary medical literature while not explaining his reasons for doing so." *In re: Ethicon Inc. Pelvic Repair Sys. Prod. Liabl. Litig.*, 2016 WL 4556807, *3 (S.D. W. Va. Aug. 31, 2016) (Memorandum Opinion and Order – *Daubert* Motion re: Brian J. Flynn, M.D.) (hereinafter "*Wave 1 Daubert Order re Flynn, MD*"). As such, Dr. Flynn's opinions regarding the medical literature are based on an unreliable methodology and should be excluded.

Additionally, Dr. Flynn offers opinions regarding his personal experience. However, to be admissible, he must establish that he followed a reliable methodology to reach his opinions regarding his personal experience. He has not. Instead, his "personal experience" is merely an ad hoc gut feeling filled with unsupported assumptions and "guesses" that are unscientific and impossible to test or investigate. Accordingly, Dr. Flynn's testimony based on his personal experiences should also be excluded.

ARGUMENT

In Wave 1, the Court concluded that Dr. Flynn did not follow a reliable methodology in reviewing the medical literature because he never addressed *any* of the contrary literature in *any* of his reports. *Wave 1 Daubert Order re Flynn, MD*, at *3. When given the opportunity to update his reports in Wave 3 and address these methodological flaws, Dr. Flynn simply reissued the same flawed reports from Wave 1. He still has not addressed any of the extensive contrary evidence. Accordingly, Dr. Flynn still has not followed a reliable methodology in reviewing the medical literature, and his opinions regarding the medical literature should be excluded.

Additionally, Dr. Flynn has offered general causation opinions purportedly based on his personal experience. Dr. Flynn has not established that he followed a reliable methodology to reach opinions based on his personal experience. Because Defendants bear the burden of establishing that Dr. Flynn's opinions are the product of a reliable methodology and they have not met this burden, his opinions based on his personal experience should also be excluded.

I. DR. FLYNN'S OPINIONS REGARDING THE MEDICAL LITERATURE ARE THE RESULT OF AN UNRELIABLE METHODOLOGY AND SHOULD BE EXCLUDED, BECAUSE HE *ONLY* REVIEWED ONE-SIDED FAVORABLE EVIDENCE AND IGNORED *ALL* CONTRARY EVIDENCE.

As required by Rule 26, an expert must disclose a report that contains "a complete statement of all opinions the witness will express and the basis for them…" Fed. R. Civ. P. 26(a)(2)(B)(i). Dr. Flynn has not complied with Rule 26 because none of his reports explain his basis for disregarding any of the extensive contrary evidence of which he was well aware. As such, he has not established that he followed a reliable methodology to reach his opinions regarding the medical literature, and these opinions must be excluded.

As demonstrated in Plaintiffs' Motion, as Dr. Flynn admitted, and as Defendants concede, in all five of his reports Dr. Flynn only discussed studies that supported his opinion that the

medical literature shows Ethicon's devices are safe and effective. Flynn 4/14/16 11:52 A.M. 24:13-15 ("I tried to choose articles that supported my opinions….") (attached as Ex. H to Memorandum) (Doc. No. 2855-8). This alone calls into question the reliability of Dr. Flynn's review, analysis, and opinion regarding the medical literature.

However, critically, when Dr. Flynn was confronted with key contrary studies during his deposition, he had no sound scientific reasoning to support his refusal to credit the studies. Instead, he had excuses akin to a high schooler with missing homework. For example, when asked why he did not address several studies non-supportive of his opinion, he testified, "I didn't have time to look at those." Flynn 4/14/16 11:52 A.M. 223:6-224:1. Another time, he testified, "I believe I've read enough…." Flynn 4/19/16 78:4-8 (attached as Ex. G to Memorandum) (Doc. No. 2855-7). Again, this clearly demonstrates the lack of any scientific method underlying Dr. Flynn's opinions.

Most importantly, however, when Dr. Flynn was asked whether the studies that contradicted his opinions might change his opinions, Dr. Flynn admitted they might. He testified that "[t]hey may have, they may not have" and "[t]here's always possibilities, but I think it's unlikely." Flynn 4/14/16 11:52 A.M. 175:1-6.

Daubert requires that an expert's opinions be derived from a reliable methodology. As the Court has previously noted, an expert must use a reliable methodology when reviewing scientific evidence, including explaining why an expert relies on certain evidence and discounts contrary evidence. Regarding an expert's treatment of contrary evidence, three possible scenarios can exist: (1) an expert may be aware of contrary evidence and simply ignore and not discuss the evidence; (2) an expert may be aware of contrary evidence and explain his reasons for discounting that evidence; and (3) an expert may not be aware of some contrary evidence and therefore not address the evidence in his Rule 26 report.

If an expert's treatment of contrary evidence falls into the first category, where the expert is aware of the contrary evidence but has not explained his reasons for discounting any of the evidence, the expert has employed an unreliable methodology under the *Daubert* analysis. *See Sanchez v. Boston Scientific Corp.*, No. 2:12-cv-05762, 2014 WL 4851989, at *12-13 (S.D. W. Va. Sept. 29, 2014) (excluding testimony of Dr. Margolis for failure to explain why he rejected Nilsson's 17-year data that was contrary to his opinions). Without some explanation for disagreement with contrary evidence, an expert's methodology is unreliable. *See Eghnayem v. Boston Scientific Corp.*, 57 F. Supp. 3d 658, 676 (S.D. W. Va. 2014) (explaining that an expert's opinion is the result of an unreliable methodology if the expert "fails to account for contrary scientific literature and instead selectively [chooses] his support from the scientific landscape.") (internal citation and quotation omitted). Here, Dr. Flynn admits, and Defendants concede, that all five of his reports failed to account for any contrary scientific literature and that he selectively chose support from the scientific landscape.

If an expert's treatment of contrary evidence falls into the second category, where the expert is aware of the contrary evidence and explains his reasons for discounting the evidence, courts have found that the expert has employed a reliable methodology for purposes of *Daubert*. The testimony is generally admissible, and any flaws in the reasoning for discounting the contrary evidence can be addressed through cross-examination. *See Wilkerson v. Boston Scientific Corp.*, No. 2:13-cv-04505, 2015 WL 2087048, *10 (S.D. W. Va. May 5, 2015) (allowing testimony of Dr. Margolis where he provided in his report and deposition "a sufficiently thorough explanation as to why he discounted certain literature, including discussions of bias in corporate-sponsored studies"). Here, this is not the case because Dr. Flynn did not provide any reasoning in any of his reports for discounting the contrary evidence.

If an expert's treatment of the contrary evidence falls into the third category, where the expert was not aware of the contrary evidence, the expert's methodology is not necessarily unreliable. A court can still find that the expert employed a sufficiently reliable methodology for purposes of *Daubert* and admit the testimony. If the court finds the expert's methodology was sufficiently reliable, the overlooked contrary evidence can be addressed through cross-examination. *See Trevino v. Boston Scientific Corp.*, No. 2016 WL 1718836, *41 (S.D. W. Va. Apr. 28, 2016) (noting that "[i]f there are certain device-specific publications that Dr. Badylak **failed to review** in preparing his expert report, the plaintiff is free to ask him about those publications on cross-examination.") (emphasis added). Here, Dr. Flynn did not simply "fail to review" some publications. Unlike Dr. Badylak in *Trevino*, Dr. Flynn was aware of the contrary evidence, reviewed the studies, and included them on his reliance list. However, he employed an unreliable methodology because he never explained why he disregarded any of the contrary evidence.

Accordingly, Dr. Flynn's treatment of contrary evidence falls into the first category and demonstrates an unreliable methodology. In Wave 1, which involved the exact same expert reports, the Court found "Dr. Flynn focused only on medical literature that supported his opinions, ignoring relevant, contrary medical literature while not explaining his reasons for doing so." *Wave 1 Daubert Order re Flynn, MD*, at *3. Despite being aware of these methodological flaws, Dr. Flynn chose not to update his Rule 26 reports for Wave 3 and instead adopted the same reports from Wave 1.

Defendants misrepresent Plaintiffs' arguments as nit-picking Dr. Flynn for "not analyz[ing] every single article." Response at 4. However, Dr. Flynn's methodological flaws are not limited to simply overlooking a few studies. As discussed in the Motion, Dr. Flynn admitted

that he purposely chose to only cite and discuss one-sided evidence, while inexplicably disregarding *all* contrary evidence of which he was well aware. Flynn 4/14/16 11:52 A.M. 24:13-15 ("I tried to choose articles that supported my opinions, so it's more what I use to make my opinions, not what I decided not to use.").

When further questioned as to the contrary evidence, Dr. Flynn admitted that "he didn't have time" to adequately review contrary evidence of which he was aware. When asked whether a number of studies that were contrary to his opinions met his criteria for whether the evidence was sufficiently important to include in his reports, Dr. Flynn admitted, "I would have to look at them more specifically. **I didn't have time to look at those.** They may have, they may not have." Flynn 4/14/16 11:52 A.M. 223:16-224:1 (emphasis added). Defendants concede that Dr. Flynn did not have time to adequately review the contrary evidence. A lack of time to adequately review the evidence does not justify an unreliable methodology.

Despite conceding that Dr. Flynn did not have time to adequately review the relevant evidence, Defendants erroneously assert that Dr. Flynn performed an "extraordinarily comprehensive" review. Response at 3. Further, in his depositions, Dr. Flynn repeatedly asserted that he had read "enough" evidence and that it was unlikely any medical literature would change his opinions. Flynn 4/19/16 75:25-76:7; 4/14/16 11:52 A.M. 178:1-6; 4/14/16 11:52 A.M. 178:16-20. Dr. Flynn's assertions that "I've read enough" further demonstrate he did not employ a reliable methodology.

In an attempt to justify Dr. Flynn's selective reliance on one-sided evidence in all five of his reports, Defendants argue that Dr. Flynn's reliance list includes "hundreds of references." Response at 3. Dr. Flynn's inclusion of these articles on his reliance list demonstrates that he was well aware of the contrary evidence, and Defendants concede that Dr. Flynn was well aware of

the contrary evidence. Defendants provide no authority for their proposition that Dr. Flynn's one-sided review of favorable evidence is cured by simply listing some contrary evidence on a reliance list. Instead, Rule 26 requires that an expert must disclose in his report all his opinions and his basis for those opinions, including his basis for disregarding contrary evidence.

In its briefing, Defendants attempt to explain *for* Dr. Flynn why he disregarded certain evidence. However, Defendants cannot cite to any explanation from Dr. Flynn's reports for his disregard of the contrary evidence. Defendants argue that Dr. Flynn chose to rely "more heavily on Level 1 evidence," implying that the contrary evidence he disregarded was not Level 1. Response at 4. However, Dr. Flynn also ignored Level 1 evidence. For example, Defendants argue that Dr. Flynn chose to cite to "numerous Cochrane reviews" in his reports. Response at 5. Dr. Flynn testified that Cochrane reviews are "very powerful" Level 1 evidence. Flynn 3/24/16 69:5-7 (attached as Ex. I to Memorandum) (Doc. No. 2855-9). However, as discussed below and in the Motion, Defendants concede that Dr. Flynn ignored Cochrane reviews that were contrary to his opinions, such as the 2014 Nambiar Cochrane review regarding TVT-Secur and the 2016 Maher Cochrane review regarding Prolift and Prolift+M.

Below, Plaintiffs discuss two examples of contrary evidence that were ignored as a result of Dr. Flynn's unreliable methodology. Importantly, these are just two examples of Dr. Flynn's systematic disregard of all contrary evidence, in all five of his Rule 26 reports.

A. Despite being aware of the "very powerful" Level 1 evidence, Defendants concede that Dr. Flynn simply ignored the negative findings from the 2014 Nambiar Cochrane review regarding the TVT-Secur device.

In Dr. Flynn's report regarding the TVT-Secur, he completely ignored Level 1 evidence that was contrary to his opinions. As discussed in Plaintiffs' Motion, the TVT-Secur is a single-incision sling as compared to multi-incision slings like the TVT-R and TVT-O slings. In his report regarding the TVT-Secur, Dr. Flynn ignored the 2014 Cochrane review by Nambiar specifically challenging the safety and effectiveness of single-incision slings such as the TVT-Secur. The 2014 Nambiar Cochrane review explained that the TVT-Secur was "withdrawn from the market because of poor results." Flynn 3/24/16 72:7-11.

Despite being aware of this powerful contrary evidence, Dr. Flynn has never explained why he discounted its findings. Dr. Flynn included the 2014 Nambiar Cochrane review on his reliance list, and Defendants concede he was aware of the study. Instead of discussing this powerful Level 1 evidence directly challenging the safety and effectiveness of TVT-Secur, Dr. Flynn selectively cited to evidence that supported his opinions, such as a different Cochrane review by Ford *regarding multi-incision slings as opposed to single-incision slings like TVT-Secur* and an older, 2011 review from Wall. Further demonstrating the unreliability of his methodology here, Dr. Flynn even refused to acknowledge that the 2014 Nambiar Cochrane review discussing the TVT-Secur would be more informative when assessing the safety and effectiveness of TVT-Secur, as opposed to a Cochrane review regarding a different type of sling device. Flynn 3/24/16 70:24-71:5.

Defendants concede that Dr. Flynn never explained why he discounted the 2014 Nambiar Cochrane review, which Dr. Flynn testified was very powerful Level 1 evidence. Defendants also concede that the Ford Cochrane review that Dr. Flynn instead discussed in his TVT-Secur report "may have not been specifically applicable to single incision slings like the TVT-Secur."

Response at 8. Dr. Flynn simply disregarded all contrary evidence in his report, including contrary evidence he was aware of and, instead, selectively cited favorable evidence, even if that evidence was not "applicable" to the product at issue.

B. Despite being aware of the evidence, Defendants concede that Dr. Flynn simply ignored evidence contrary to his opinions regarding Prolift and Prolift+M, including negative findings from Level 1 evidence, such as the 2016 Maher Cochrane review regarding mesh based repairs for prolapse.

Similarly, Dr. Flynn was aware of numerous articles that reached conclusions contrary to his opinions regarding the Prolift and Prolift+M devices. Additionally, Defendants admit that Dr. Flynn was aware of the 2016 Maher Cochrane review and explained that "he inadvertently neglected to update his reliance list to include it." Response at 9-10. In contrast to Dr. Flynn's opinions that the Prolift and Prolift+M mesh products are safe and effective for the treatment of pelvic organ prolapse, the 2016 Maher Cochrane review concluded that, "The risk-benefit profile means that transvaginal mesh has limited utility in primary surgery [to treat vaginal prolapse]." Flynn 4/14/16 11:52 A.M. 222:8-12. Apparently, Dr. Flynn also "inadvertently neglected to update" his report to explain why he disregarded the findings from the study.

Likewise, Dr. Flynn never explained in his report why he disagreed with the negative findings from other studies of which he was aware and that he included on his reliance list, but that were contrary to his opinions, including the 2012 study by Stanford, the 2010 study by Iglesia, and the 2009 study by Diwadkar. *See* Reliance List (attached as Ex. K to Memorandum) (Doc. No. 2855-11); Memorandum at 10-11. Defendants concede as much. Dr. Flynn likely did not disclose his basis for discounting contrary evidence because he simply disagreed with the conclusions. For example, regarding the 2012 Stanford study that concluded native tissue repairs were as efficacious as mesh repairs for anterior pelvic organ prolapse, Dr. Flynn was asked, "Do you think this study is reliable, or have an opinion one way or the other?" Dr. Flynn responded,

"I don't have an opinion. I'm not that familiar with that study." Flynn 4/14/16 11:52 A.M. 104:19-23. This evidence undermines Dr. Flynn's opinion that mesh-based repairs are necessary because alternative procedures, such as native tissue repairs, are not effective. Plaintiffs still do not know why he discounts this and other contrary evidence, except that the evidence is contrary to his opinions.

It is not Plaintiffs' burden to present Dr. Flynn with each piece of evidence that is contrary to his opinion. Rather, Rule 26 and *Daubert* require an expert to demonstrate that they employed a reliable methodology which includes disclosing his basis for discounting certain evidence in favor of other evidence. Of course, an expert need not discuss in his Rule 26 reports *every* piece of evidence that exists, but Dr. Flynn has not explained his disagreement with *any* of the contrary evidence. Dr. Flynn simply "disagreed" with the studies because they did not support his opinions. This is not a reliable methodology.

II. DR. FLYNN'S OPINIONS REGARDING HIS PERSONAL EXPERIENCE ARE NOT SUPPORTED BY ANY RELIABLE METHODOLOGY AND SHOULD BE EXCLUDED.

In addition to his opinions regarding his purported "literature review," Dr. Flynn insists that he reached opinions based on his "personal experience." However, while an expert might be *qualified* through his personal experience to offer expert testimony, he still must establish that he followed a reliable methodology in reaching his opinions. The Court does not have to simply "take his word for it." Here, Dr. Flynn has not disclosed any reliable methodology and instead provides vague, untestable assertions. Additionally, Dr. Flynn does not reconcile his statements from outside of this litigation that are contrary to his opinions here.

In his own practice, he contradicts the opinions he offers here. For example, in his litigation report here, he concludes that the TVT-O is safe and effective for treatment of stress urinary

incontinence ("SUI") in women. Yet, he testified that, "Sitting here today with the information and experience I had with both products, no, **there'd be no reason I would use a TVT-O over the TVT-Abbrevo** unless the patient had requested that." Flynn 4/14/16 8:42 A.M. 44:3-6 (attached as Ex. J to Memorandum) (Doc. No. 2855-10). He explained he does not use the TVT-O because the TVT-Abbrevo has less transient leg pain, shorter convalescence, and quicker return to work and normal daily living. *Id.* at 28:22-31:8. Dr. Flynn's litigation opinion that TVT-O is safe and effective is contradicted by his own testimony that now, with the availability of a safer, better product, there is no reason he would use TVT-O. Despite Defendants' argument, Dr. Flynn does not simply have a *preference* for one product over the other – he testified there is now no reason to use the TVT-O at all.

Further, Dr. Flynn's own publications outside of this litigation contradict his litigation-driven opinions here. For example, in his 2013 article discussing his personal experience with surgical management of mesh-related complications, he stated that he has seen "an alarming increase" and an "escalation in the severity" of mesh complications. Flynn 4/14/16 11:52 A.M. 144:3-145:13. Dr. Flynn did not discuss his own paper in any of his reports here. Likewise, Dr. Flynn did not explain how the "alarming increase" and "escalation in severity" of mesh complications affected his opinions here. His failure to explain his own contrary statements – statements made outside of the litigation context – further indicates that he employed an unreliable methodology.

In addition to these unexplained contradictions between his personal experience and his opinions here, Dr. Flynn's "personal experience" with these products is not sufficiently reliable. Dr. Flynn does not know how often women suffer complications from these mesh devices. For example, when asked how many TVT-Secur products he has revised or explanted, Dr. Flynn

admitted that he does not know the answer. He testified, "I would be guessing." Flynn 3/24/16 13:11-17. Dr. Flynn has explained that this is because he does not "keep track of what the product was necessarily." Flynn 3/24/16 12:8-15. As such, he does not know how often any of these products are injuring women. Based on his own admissions, Dr. Flynn's "personal experience" is not a reliable basis for his opinions that these products are safe. He is simply "guessing" as to his personal experience regarding the safety of these products.

Dr. Flynn's opinions based on his personal experience are the product of an unreliable methodology. Instead, he is simply guessing at his own experience and has failed to explain any of his published statements that are contrary to his opinions here. As Defendants have failed to carry their burden to establish that Dr. Flynn followed a reliable methodology in reaching his expert opinions regarding his personal experience, these opinions should be excluded.

III. DR. FLYNN'S OPINIONS ABOUT DEGRADATION SHOULD BE EXCLUDED BECAUSE HE IS UNQUALIFIED AND HIS OPINIONS ARE UNSUPPORTED AND ARE NOT THE PRODUCT OF A RELIABLE METHODOLOGY.

Dr. Flynn seeks to testify that no evidence exists regarding the propensity of mesh to degrade and injure women. Dr. Flynn admits he is not qualified to testify about these topics and has not reviewed the relevant evidence. In Wave 1, Dr. Flynn was confronted with evidence that directly contradicted his opinions, and the Court excused his failure to review the relevant evidence. Yet, given the opportunity in Wave 3 to address the contradictory evidence, he instead simply adopted his Wave 1 reports and continues to *completely ignore* the contrary evidence. This stubborn refusal to address contrary evidence cannot be sanctioned and demonstrates an unreliable methodology. Accordingly, his opinions that *no* evidence exists regarding degradation must be excluded.

Dr. Flynn has specifically testified that he is *not* an expert in pathology and has not done

any lab work, bench testing, or biomechanical scientific research on any of these products. Flynn 10/30/14 139:7-10 (attached as Ex. L to Memorandum) (Doc. No. 2855-12); Flynn 8/29/14 9:15-17 (attached as Ex. M to Memorandum) (Doc. No. 2855-13); Flynn 4/19/16 66:4-7. Nonetheless, Defendants contend that Dr. Flynn is qualified to offer opinions "focused on clinical aspects of alleged degradation" solely based on the Court's earlier ruling. Response at 14. While the Court has allowed medical doctors like Dr. Flynn to offer opinions regarding degradation from a clinician's perspective, Dr. Flynn has specifically testified that he is *not qualified* to discuss clinical aspects related to the mesh design.

The parties' biomaterials and pathology experts have offered opinions regarding the interplay among mesh design, degradation, infection, and other clinical outcomes, but Dr. Flynn is out of his expertise here. For example, he does not know whether degradation potentiates infection, and Dr. Flynn has admitted that he is not qualified to make that assessment. Flynn 4/19/16 79:8-15 ("I'm uncertain on what the implications of the cracking would be."). When asked whether infection was related to the mesh design, he testified: "whether that is related to the design of the meshes, that's something a materials scientist might know. But I'm not familiar with that." Flynn 8/29/14 52:16-25. Dr. Flynn has admitted he is not qualified to offer an opinion regarding these issues.

Even assuming arguendo that Dr. Flynn is qualified, "an analysis of the reliability of that expert's methodology is required." *Sanchez*, 2014 WL 4851989 at *6 (quoting *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S.579, 597 1993)). "Qualifications alone do not guarantee reliability". *Id.* (internal citation omitted). Dr. Flynn's opinions regarding mesh design, degradation, and clinical outcomes are not the product of a reliable methodology because he has refused to review the relevant literature. He cannot be allowed to testify about the biomaterials evidence if he *refuses*

to review the actual evidence.

In his Wave 1 reports, Dr. Flynn stated that he has "never read or seen a single peer-reviewed published article or seen any cited by plaintiffs' experts that showed any clinical effect of degradation." *See, e.g.*, TVT Report at 27 (attached as Ex. B to Memorandum) (Doc. No. 2855-2); Flynn 4/19/16 75:25-76:7. However, in his Wave 1 deposition, Dr. Flynn was presented with published medical literature that showed that "cracking of the degraded material indicated a contribution to clinically important mesh stiffening and deformation." Flynn 4/19/16 77:4-17. When asked whether he would have liked to have reviewed the article showing clinical effects from degradation prior to writing his report, he responded that he had "read enough articles on degradation." Flynn 4/19/16 75:25-76-7.

Instead of reviewing the relevant evidence, Dr. Flynn simply adopted his Wave 1 reports. While the Court excused his failure to review the evidence in Wave 1, he cannot be allowed to continue to stick his head in the sand. Dr. Flynn's stubborn refusal to review evidence contradicting his opinions directly sheds light on the unreliability of his method, and his testimony should be excluded.

IV. DR. FLYNN'S ANALYSIS OF LASER CUT MESH (LCM) IS UNSUPPORTED, UNRELIABLE, AND CONTRADICTED BY THE EVIDENCE.

Dr. Flynn offers additional opinions that the design and manufacturing process of the mesh, specifically regarding how the mesh is cut, does not have any clinical implications. As discussed above, Dr. Flynn has admitted and Defendants concede that he is not qualified regarding the materials science or design aspects of the mesh. However, Defendants argue he may potentially be qualified to testify from his personal experience as to the clinical outcomes related to how the mesh was cut. To do so, however, would require Dr. Flynn to establish that he applied a reliable methodology in reaching this opinion. Dr. Flynn has not and cannot do so.

Experts cannot base their opinions on unsupported assumptions. *See Hathaway v. Bazany*, F.3d 312, 318 (5th Cir. 2007). Here, Dr. Flynn makes several unsupported assumptions to reach his opinion that there is no clinical impact from the manufacturing and cutting process. First, he assumes that he can compare devices that were only available in mechanically cut mesh to different devices that were only available in laser cut mesh to establish the safety of completely different products. Next, he assumes certain studies used *only* laser cut *or* mechanically cut mesh. However, he was unable to identify which mesh was used in any specific study, because such information is not available. Flynn 4/19/16 118:13-119:18. Instead, he incorrectly assumed that all studies after 2006 used only laser cut mesh. In fact, Dr. Flynn does not know how many mechanically cut versus laser cut products he has used. Flynn 4/19/16 136:7-8; Flynn 4/19/16 156:23-157:1.

Without some explanation or basis, he cannot simply assume that it is reliable to compare completely different devices to establish the safety of the products here. Likewise, he cannot simply assume all devices used laser cut mesh after a certain date without some reliable basis. In fact, in deposition, Dr. Flynn was presented with evidence that contradicted his assumption that all products after 2006 used only laser cut mesh, and he admitted his assumption may be incorrect. When confronted with an internal Ethicon email stating that even after the launch of laser cut mesh 90 percent of the TVT and TVT-O products on the market were still mechanically cut, Dr. Flynn admitted, "That's what it says, and **that may be true**…" Flynn 4/19/16 120:23-121:13.

Dr. Flynn did not follow a reliable methodology in reaching his opinions regarding the safety of the five products here related to the manufacturing processes because he based these opinions on unsupported assumptions. This testimony should be excluded.

V. DR. FLYNN'S OPINIONS REGARDING THE ADEQUACY OF ETHICON'S WARNINGS SHOULD BE EXCLUDED BECAUSE HE IS UNQUALIFIED AND HAS NO RELIABLE BASIS.

Dr. Flynn offers numerous opinions regarding the *adequacy* of Ethicon's warnings. While the Court has allowed expert testimony from medical doctors regarding what complications they have seen in their practice and whether those warnings were included on the label, the Court has consistently held that medical doctors are not qualified to opine as to the *adequacy* of warnings without some additional qualifications, for example, regarding the regulatory requirements for a label. *See Trevino*, 2016 WL 1718836, at *45 (holding that "without additional expertise in the specific area of product warnings, a doctor … is not qualified to opine that a product warning was adequate …").

Dr. Flynn is not qualified to opine as to the regulatory requirements regarding warnings or Ethicon's own internal standards. He admits he is not qualified here, and Defendants concede as much. Dr. Flynn can testify that certain complications are listed in the label, but he cannot testify as to the adequacy of the label. These opinions should be excluded.

VI. DR. FLYNN'S IMPERMISSIBLE LEGAL CONCLUSIONS MUST BE EXCLUDED.

Dr. Flynn offers numerous conclusions regarding the legal issues here. Defendants argue that Dr. Flynn's opinion that Ethicon "adequately warned" is not a legal conclusion. Of course, this is the ultimate issue for the jury to decide. These and other legal opinions should be excluded. *See United States v. McIver*, 470 F.3d 550, 562 (4th Cir. 2006) (holding that "opinion testimony that states a legal standard or draws a legal conclusion by applying law to the facts is generally inadmissible.").

CONCLUSION

Dr. Flynn's opinions regarding the medical literature should be excluded because he purposely ignored all contrary evidence. When given the opportunity to fix this fatal methodological flaw, he simply reissued the same deficient reports from Wave 1. Additionally, Dr. Flynn has offered general causation opinions purportedly based on his personal experience. Dr. Flynn has not established that he followed a reliable methodology to reach opinions based on his personal experience. Defendants have not met their burden to establish that any of Dr. Flynn's opinions are the product of a reliable methodology and they should be excluded.

Respectfully submitted this 21st day of October, 2016.

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CERTIFICATE OF SERVICE

I hereby certify that I filed the foregoing **REPLY MEMORANDUM IN SUPPORT OF PLAINTIFFS' MOTION TO EXCLUDE THE GENERAL CAUSATION OPINIONS OF BRIAN J. FLYNN, MD**, on October 21, 2016, using the Court's CM/ECF filing system, thereby sending notice of said filing to all counsel.

/s/ Jenelle Cox